



Office of the Director
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

**Biorepository Coordinating Committee
Workshop on
Biospecimen Access and Ethical, Legal, and Policy Issues**

June 23-24, 2005

Bethesda North Marriott Hotel and Conference Center
North Bethesda, Maryland

APPENDIX C:

AGENDA

This landmark workshop will bring together leaders from the national and international academic communities, private sector, and government to provide recommendations for ethical policy guidelines that will govern the collection and use of human biological specimens and associated data in National Cancer Institute (NCI)-sponsored resources/repositories. The goal is to facilitate the collection and future use of resource/repository specimens and associated data while protecting the subjects from whom the specimens and data are obtained.

Thursday, June 23

7:00 a.m. - 8:00 a.m.	Registration	<i>Foyer F & G</i>
8:00 a.m. - 12 noon	Plenary Session	<i>Salon F & G</i>
8:00 a.m. - 8:15 a.m.	<i>Welcoming Remarks</i> Rihab Yassin, Ph.D. Julie Schneider, D.Phil. Anna Barker, Ph.D.	
8:15 a.m. - 8:45 a.m.	<i>Objectives of the Workshop</i> Anna Barker, Ph.D.	
8:45 a.m. - 9:15 a.m.	<i>Chair's Remarks</i> Arthur Caplan, Ph.D.	
9:15 a.m. - 9:45 a.m.	<i>Regulations 101: The Fundamentals</i> Glen Drew, J.D., M.S.	
9:45 a.m. - 10:15 a.m.	<i>Overview of Existing Repository Practice Guidelines and Open Issues</i> Mark E. Sobel, M.D., Ph.D.	
10:15 a.m. - 10:30 a.m.	<i>Questions and Answers</i> All Panel	
10:30 a.m. - 10:45 a.m.	Coffee Break	

Thursday, June 23 (continued)

10:45 a.m. - 11:15 a.m.	<i>The International Perspective</i> Bernice S. Elger, M.D., Ph.D.	
11:15 a.m. - 11:30 a.m.	<i>Definitions</i> Marianna J. Bledsoe, M.A.	
11:30 a.m. - 11:45 a.m.	<i>Charge to the Committee, Breakout Objectives</i> Arthur Caplan, Ph.D.	
11:45 a.m. - 12 noon	<i>Questions and Answers</i> All Panel	
12 noon - 1:00 p.m.	Lunch Break	
1:00 p.m. - 3:15 p.m.	Roundtable Breakout Sessions	
Roundtable 1	Informed Consent <i>Chair:</i> Eric Kodish, M.D. <i>Co-Chair:</i> Marianna J. Bledsoe, M.A. <i>Writer:</i> Margaret Feerick, Ph.D. <i>Participants:</i> Bette-Jane Crigger, Ph.D.; Claudia Gaffey, M.D.; J. Milburn Jessup, M.D.; Paula Kim; Lori P. Knowles, M.A., L.L.M.; Virginia A. LiVolsi, M.D.; David Shore, M.D.; Celeste Whitewolf, J.D. <ul style="list-style-type: none">• Principles of Subject Protection• Type, Specificity, and Content of Consent• Timing of Consent• Termination of Participation/Withdrawal of Consent• Waiving of Consent• Recontacting Human Subjects• Special Informed Consent Issues	<i>Great Falls Room</i>
Roundtable 2	Privacy, Confidentiality, and Data Security Protections <i>Chair:</i> Mark E. Sobel, M.D., Ph.D. <i>Co-Chair:</i> Sheila E. Taube, Ph.D. <i>Writer:</i> Frances McFarland-Horne, Ph.D., M.A. <i>Participants:</i> Katherine R. Calvo, M.D., Ph.D.; Anita L. Allen-Castellitto, Ph.D., J.D.; Liza Dawson, Ph.D.; Martin L. Ferguson, Ph.D.; Andrew Glass, M.D.; Lora A. Kutkat, M.S., M.P.H.; Larry I. Palmer, L.L.B.; Judy Perotti, M.S.; Hilary M. Wandall, J.D., M.B.A. <ul style="list-style-type: none">• Data Collection, Storage, and Management• Data Security• Protecting Privacy and Confidentiality of Identifiable Information• Releasing Identifiable Specimens and Data• Disclosing Research Results and Minimizing Social Harms	<i>Seneca Boardroom</i>

Thursday, June 23 (continued)

Roundtable 3

IRBs and Governance

Middlebrook Room

Chair: Timothy J. O’Leary, M.D., Ph.D.

Co-Chair: Linda Weiss, Ph.D.

Writer: Kerry Kemp

Participants: Debra Aronson, J.D.; Kathleen Bem, M.S.; Glen Drew, J.D., M.S.; Jon F. Merz, Ph.D., J.D., M.B.A; Pearl O’Rourke, M.D.; Rebekah S. Rasooly, Ph.D.; Ruby T. Senie, Ph.D., M.A.; Westley Sholes, M.P.A.; Jennifer Strasburger

- Local IRBs
- Central IRBs
- Bioethics Advisory Boards

Roundtable 4

Ownership Legal and Policy Issues

Oakley Room

Chair: David Korn, M.D.

Co-Chair: Wendy Patterson, J.D.

Writer: David W. Conrad, Ph.D., M.B.A.

Participants: Jeanne C. Beck, Ph.D.; Annette Levey, J.D.; Mary Anderlik Majumder, Ph.D., J.D.; Karen Maschke, Ph.D.; Karen Maurey, M.S.; Arti K. Rai, J.D.; Richard L. Schilsky, M.D.; Mary Lou Smith, J.D.; Bruce W. Wachholz, Ph.D.

- Ownership Rights of Specimen Contributors, Investigators, and Institutions
- Ownership of Financial Interests and Associated Conflicts
- Ownership of Intellectual Property Rights
- Ownership of Products and Benefits

Roundtable 5

Access to Specimens and Data

Timberlawn Room

Chair: Patricia Deverka, M.D., M.S., M.B.E.

Co-Chair: Rihab Yassin, Ph.D.

Writer: Roberta Haber, Ph.D.

Participants: Patricia Charache, M.D.; Thomas L. Croxton, M.D., Ph.D.; Lynn G. Dressler, Dr.P.H.; Bernice S. Elger, M.D., Ph.D.; Ian Fore, D.Phil.; Elizabeth Hammond, M.D.; Kevin Krenitsky, M.D.; Michael Pellini, M.D., M.B.A.; Elizabeth Read-Connole, Ph.D.; Karl Schwartz, M.F.A.; Jeffrey R. Smith, M.D., Ph.D.

- Investigator Access to Samples and Research Information
- Patient Access to General and Personal Research Information
- Public Access to Research Information
- Data Sharing and Dissemination of Research Findings

Thursday, June 23 (continued)

3:15 p.m. - 3:30 p.m.

Coffee Break

3:30 p.m. - 6:00 p.m.

Plenary Session

Salon F & G

Report From Breakout Chairs on Progress and Issues Requiring Further Discussion

Chair: Arthur Caplan, Ph.D.

Reports, 20 Minutes; Q & A, 10 Minutes

3:30 p.m. - 4:00 p.m.

Informed Consent

Eric Kodish, M.D.

4:00 p.m. - 4:30 p.m.

Privacy, Confidentiality and Data Security Protections

Mark E. Sobel, M.D., Ph.D.

4:30 p.m. - 5:00 p.m.

IRBs and Governance

Timothy J. O'Leary, M.D., Ph.D.

5:00 p.m. - 5:30 p.m.

Ownership Legal and Policy Issues

David Korn, M.D.

5:30 p.m. - 6:00 p.m.

Access to Specimens and Data

Patricia Deverka, M.D., M.S., M.B.E.

Friday, June 24

8:00 a.m. - 10:00 a.m.

Roundtable Breakout Sessions

Focus: Discussion of Unresolved Issues

Roundtable 1

Informed Consent

Great Falls Room

Roundtable 2

Privacy, Confidentiality, and Data Security
Protections

Seneca Boardroom

Roundtable 3

IRBs and Governance

Middlebrook Room

Roundtable 4

Ownership Legal and Policy Issues

Oakley Room

Roundtable 5

Access to Specimens and Data

Timberlawn Room

10:00 a.m. - 10:20 a.m.

Coffee Break

10:20 a.m. - 12:30 p.m.

Plenary Session

Salon F & G

Report From Breakout Chairs on Progress

Chair: Arthur Caplan, Ph.D.

Reports, 15 Minutes; Q & A, 5 Minutes

10:20 a.m. - 10:40 a.m.

Informed Consent

Eric Kodish, M.D.

10:40 a.m. - 11:00 a.m.

Privacy, Confidentiality, and Data Security Protections

Mark Sobel, M.D., Ph.D.

11:00 a.m. - 11:20 a.m.

IRBs and Governance

Timothy O'Leary, M.D., Ph.D.

11:20 a.m. - 11:40 a.m.

Ownership Legal and Policy Issues

David Korn, M.D.

11:40 a.m. - 12 noon

Access to Specimens and Data

Patricia Deverka, M.D., M.S., M.B.E.

12 noon - 12:30 p.m.

Wrap-up, The Next Steps

Arthur Caplan, Ph.D.

Anna Barker, Ph.D.

12:30 p.m.

Adjournment